REMARKS AND RESPONSE TO RESTRICTION REQUIREMENT

The Examiner has required restriction of the invention under 35 U.S.C. 121 to one of the following groups:

Group I: Claims 1-8 and 13-15, drawn to methods for determining the mRNA levels of one or more molecules associated with evaluation of risk and diagnosis of spontaneous abortion, classified in Class 435, subclass 6.

Group II: Claims 1-8 and 13-15, drawn to methods for determining the protein levels of one or more molecules associated with evaluation of risk and diagnosis of spontaneous abortion, classified in Class 435, subclass 7.1.

Group III: Claims 1-8 and 13-15, drawn to methods for determining the mRNA levels of one or more molecules associated with evaluation of treatment of spontaneous abortion, classified in Class 435, subclass 6.

Group IV: Claims 1-8 and 13-15, drawn to methods for determining the protein levels of one or more molecules associated with evaluation of treatment of spontaneous abortion, classified in Class 435, subclass 7.1.

If Applicants elect Group I, II, III or IV, the Examiner further requires a species election for the molecule among the species of:

Species:
- A) VCAM;
- B) P-selectin,
- C) E-selectin,
- D) IL-2,
- E) IL-10,
- F) IL-12,
- G) IL-11,
- H) TNFα,
- I) IL-1ß,
- J) TGF,
- K) RANTES,
- L) IL-6,

M) IFN-γ,
N) B7.1,
O) B7.2,
P) CD4,
Q) CD8,
R) GL50,
S) ICOS.

It is the Examiner's position that inventions I and II and inventions III and IV are patentably distinct because they are methods which are mutually exclusive, in that they reach separate and distinct endpoints, and in that they employ unrelated steps to accomplish these mutually exclusive endpoints.

Applicants respectfully submit that the Restriction Requirement set forth by the Examiner contains an error, in that Groups III and IV should encompass claims 9-12 and 13-15 instead of claims 1-8 and 13-15. The Examiner states that the invention of Groups III and IV are drawn to methods for determining the mRNA or protein levels of one or more molecules associated with evaluation of treatment of spontaneous abortion. Claims 9-13, and not claims 1-8, are directed to a method for determining whether a treatment of a subject for a spontaneous abortion is having the desired effect. Accordingly, Applicants believe that the Restriction was intended to be between Group I (claims 1-8 and 13-15), Group II (claims 1-8 and 13-15), Group III (claims 9-12 and 13-15) and Group IV (claims 9-12 and 13-15).

Applicants hereby elect the Group I invention (claims 1-8 and 13-15, drawn to methods for determining the mRNA levels of one or more molecules associated with evaluation of risk and diagnosis of spontaneous abortion) under 35 U.S.C. §121 for prosecution in the present application, ***with traverse***. Applicants traverse the restriction requirement to the extent that Groups I and II should be reformed as a single group, newly formed group I, containing claims 1-8 and 13-15. Applicants hereby elect ***newly formed Group I*** for prosecution on the merits. Applicants' grounds for traversal are set forth below.

It is respectfully submitted that searches necessary for Groups I and II (newly formed Group I) would be co-extensive and therefore would constitute no serious burden on the Examiner. More specifically, Groups I and II each include Claims 1-8 and 13-15, with the individual groups being specific for the endpoint measured in evaluating the risk and diagnosis of

spontaneous abortion, the endpoints being amount of the molecule of interest, whether measured by mRNA levels (Group I) or protein levels (Group II). Applicants submit that a search with respect to the levels of the selected molecule, i.e., VCAM, would identify art relevant to the remaining claims of Groups I and II. As such, Applicants respectfully request that Groups I and II be reformed as a single group containing Claims 1-8 and 13-15.

It is further respectfully submitted that Applicant has presented allowable generic claims, claims 1 and 5, which are generic to the claims set forth in groups I-II proposed by the Examiner. Claims 1 and 5 are drawn to detecting the presence or level of mRNA or polypeptide. It is Applicants' position that given the presence of claims 1 and 5, which are generic to groups I-II proposed by the examiner a restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect ***newly formed Group I***, claims 1-8 and 13-15.

It is Applicants' position that while a species election may be proper among claims 1-8 and 13-15 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. Applicants further provisionally elect ***Group I*** for search purposes only.

Applicants further elect the species group of ***VCAM*** for search purposes only.

It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

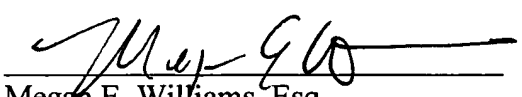
Applicants reserve the right to traverse the restriction between the non-elected groups in this or a separate application.

SUMMARY

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. GNN-010CPDV from which the undersigned is authorized to draw.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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